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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,722	10/23/2003	Jerome B. Zeldis	9516-078-999	2389

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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
OLSON, ERIC	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 08/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,722	ZELDIS ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

This application claims benefit of provisional application 60/421004, filed October 24, 2002. Claims 1-26 are pending in this application and subjection to restriction herein.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 6 in part and 7 in full drawn to a method of treating nociceptive pain by administering a compound of formula (I), (II), or (III), classified in class 514, subclass 256, 266.1, 309, 328, 372, 373, 408, 416, or 417, for example.

II. Claims 6 in part and 8-11 in full drawn to a method of treating nociceptive pain by administering a compound of formula (I), (II), or (III), classified in class 514, subclass 256, 266.1, 309, 328, 372, 373, 408, 416, or 417, for example.

III. Claims 24-26 drawn to a pharmaceutical compound comprising a selective cytokine inhibitor and an additional active agent, classified in class 514, subclass 406 or 568, for example.

Claims 1-5 and 12-23 link inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. Upon the indication of allowability of the linking claims, the restriction requirement as to the

linked inventions shall be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related methods of treating pain. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the invention of group I is directed to the treatment of nociceptive pain

while the invention of group II is directed to a method of treating neuropathic pain. These two kinds of pain differ in their causes, mechanisms, and methods of treatment. Nociceptive pain is caused by the transmission of pain signals from the nociceptors in response to a painful stimulus such as a cut, burn, inflammation, or other form of tissue damage. Neuropathic pain is caused by an abnormality in the nervous system, such as damage to a nerve, and does not correspond to any actual external stimulus. Thus therapeutic approaches to these two types of pain differ considerably. For the treatment of nociceptive pain, treating the underlying painful stimulus, such as an infection causing inflammation, is often sufficient to remove the pain. Neuropathic pain, on the other hand, fails to respond to many of the treatments used for nociceptive pain. Therefore a method of treating neuropathic pain is expected to possess a materially different design, mode of operation, function, and effect from a method of treating nociceptive pain.

Inventions I-II are related to invention III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the methods of groups I-II could be practiced with existing analgesic drugs, such as non-steroidal anti-inflammatory drugs or opioids. Thus the inventions of groups I-II are distinct from those of group III.

The search field for a composition is non-coextensive with the search field for a method of treating a patient employing the same composition. A reference to the composition herein would not necessarily be a reference to the method of treatment herein under 35 USC 103 because a search indicating the process or method is novel or unobvious would not extend to a holding that the product is novel or unobvious whereas a search indicating that the product is known or would have been obvious would not extend to a holding that the process or method is known and would have been obvious. Note that the search is not limited to patent files. Thus an undue burden on the Office is seen for the search of all inventions herein, as discussed in the Requirement for Restriction above.

Because these inventions are distinct for the reasons given above and the search required for Groups I-II is not required for Group III, restriction for examination purposes as indicated is proper.

Election of Species

This application contains claims directed to the following patentably distinct species:

(i) A plurality of molecular structures disclosed in instant claims 17, 19, and 21,

(ii) a plurality of disorders disclosed in instant claims 7-12.

The species are independent or distinct because the various chemical structures of instant claims 17, 19, and 21 possess different steric and electronic properties and are expected to interact differently with their molecular target, and the disorders

disclosed in instant claims 7-12 have different causes and mechanisms of pathogenesis, and are linked only by including pain as a symptom.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of:

(1) a single therapeutic agent; and

(2) a single disease or condition to be treated

for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-6 are generic to a plurality of diseases and therapeutic agents classified across class 514. The disclosed therapeutic agents possess a great diversity of chemical structures. It is noted that a reference to one individual agent would not be a reference to another individual agent under 35 U.S.C.103.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103(a) of the other invention.

Because the above election/restriction requirement is complex, a telephone call to applicant's agent to request an oral election was not made. (See MPEP 812.01)

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday through Friday from 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eric Olson

Patent Examiner
AU 1623
8/9/06

Anna Jiang

8/14/06

Supervisory Patent Examiner
AU 1623